

### **REMARKS**

Claim 11 is pending in this application. Claims 1-10 and 12-23 are canceled herein without prejudice. Claim 11 is amended herein for clarity to more particularly define the invention. Support for these amendments is found throughout the specification and the language of the original claims, as set forth below (including at least, e.g., on page 7, line 13, on page 23, lines 24-27; and on page 28, line 12 and lines 18-20). No new matter is added by these amendments and their entry and consideration are respectfully requested. In light of these amendments and the following remarks, applicants respectfully request reconsideration of this application and allowance of the pending claims to issue.

Applicants wish to draw the Examiner's attention to the new docket number, 5470.451, by which this application is now identified.

#### **I. Sequence Listing**

The Office Action states that the present application fails to comply with the requirements for Sequence Listings in a patent application.

Enclosed with this response is a Sequence Listing in paper copy and computer readable form (CRF) and a copy of the Notice to Comply with Requirements for Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures that was attached to the Office Action. Applicants state that the content of the paper copy and of the computer readable form of the Sequence Listing is the same and includes no new matter. Applicants respectfully request entry of the paper copy of the Sequence Listing into the present application, after the last page containing the Abstract.

#### **II. Rejection under 35 U.S.C. § 112, first paragraph**

The Office Action states that claim 11 is rejected under 35 U.S.C. § 112, first paragraph,

as allegedly lacking enablement.

Claim 11 as presented herein recites a method of treating latent HIV infection in a human subject in need of such treatment, comprising administering to the subject: a) an amount of an inhibitor of HDAC1 activity, said amount being effective to inhibit repression of HIV transcription, and b) a therapeutically effective amount of one or more anti-retroviral drugs.

The method of claim 11 is adequately enabled by the teachings of the instant specification. In particular, applicants provide herein, as evidence of such enablement, the results of an *in vivo* study demonstrating the efficacy of treatment of latent HIV infection in a subject according to the claimed methods of this invention. Such evidence is included herewith in a Declaration under 37 C.F.R. § 1.132 of Dr. David M. Margolis. Specifically, Dr. Margolis states in his Declaration that studies were carried out under his direction and supervision wherein four human subjects infected with HIV augmented their highly-active antiretroviral therapy (HAART) by the addition of 90  $\mu$ g of enfuvirtide subcutaneously twice daily for four to six weeks. Two doses of 500-750 mg of oral valproic acid were then added to their daily treatment regimen. Latent infection of resting CD4+ T cells was quantified before augmented treatment and after 12 weeks of valproate therapy by limiting dilution culture of resting CD4+ T cells after *ex vivo* activation. Results of these studies showed that the frequency of resting CD4+ T cell infection was stable before addition of enfuvirtide and valproic acid, but declined thereafter and this decline was significant in three of the four patients (mean reduction 75%, range 68% to >84%).

As set forth in the enclosed Declaration, these studies and the data described by Dr. Margolis clearly demonstrate that a method of treating latent HIV infection in a human subject in need of such treatment, comprising administering to the subject: a) an amount of an inhibitor of HDAC1 activity, said amount being effective to inhibit repression of HIV transcription, and b) a

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therapeutically effective amount of one or more anti-retroviral drugs can be carried out by one of ordinary skill in the art without undue experimentation. Thus, applicants believe the method of this invention is enabled and that this rejection has been overcome and applicants respectfully request its withdrawal and allowance of the pending claims to issue.

For all the reasons set forth above, applicants believe that the pending rejections in this application have been overcome and their withdrawal is respectfully requested. The Examiner is invited and encouraged to contact the undersigned directly if such contact will expedite the prosecution of the pending claims to issue.

A check in the amount of \$225.00, as the fee for a two month extension of time for a small entity, is enclosed. This amount is believed to be correct. However, the Commissioner is authorized to charge any deficiency associated with this filing or credit any overpayment to Deposit Account No. 50-0220.

Respectfully submitted,



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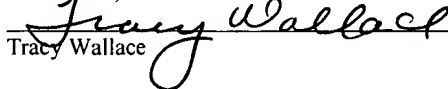
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**CERTIFICATE OF EXPRESS MAILING  
UNDER 37 CFR 1.10**

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Date of Deposit: July 17, 2006

I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

  
Tracy Wallace